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November 1, 2017

The Honorable Sherry R. Fallon
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Allergan, Inc. v. Taro Pharm. Indus. Ltd. et al.*
C.A. No. 17-663 (VAC) (SRF) (Consol.)

Dear Judge Fallon:

Pursuant to the Court's October 16, 2017 Order setting a Discovery Dispute Teleconference for November 6, 2017, Allergan submits this letter to seek the Court's assistance in resolving two issues relating to the parties' proposed protective order.¹ The first issue concerns Taro's attempt to deny Allergan's in-house counsel access to its ANDA by designating it Highly Confidential. The second issue relates to Taro's request to allow its non-attorney IP personnel access to Allergan's Confidential information.

I. The Court should permit Allergan's in-house counsel access to the entire ANDA.

These consolidated actions arise out of Taro's attempt to market a generic version of Allergan's Aczone[®] 7.5% product, a topical gel for treating acne. Taro produced its ANDA on July 20, 2017 and August 1, 2017, making both productions under D. Del. L.R. 26.2, which allows access only to counsel of record. Allergan sent Taro a proposed protective order on August 9, 2017, seeking to establish a mechanism for Allergan's in-house counsel (and experts) to review the ANDA. After a nearly seven-week delay,² Taro responded on September 25, agreeing with most provisions but taking the position that Taro may freely designate its ANDA Highly Confidential, rendering it inaccessible to Allergan's in-house counsel.

The parties agree that Confidential information may be accessed by up to two in-house counsel of the receiving party for the sole purpose of litigating the case, and that no in-house counsel will have access to Highly Confidential information. Ex. A. ¶¶ 13, 14(b), 15. The parties disagree, however, as to what constitutes Confidential and Highly Confidential information. Ex.

¹ See Ex. A, at ¶¶ 2, 3, 11, 14(b), for the parties' competing proposals of the protective order.

² See D.I. 27, at 5, for further detail on Taro's repeated delays regarding access to the ANDA.

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A ¶¶ 2, 3, 11. To prevent improper designation and to minimize unnecessary disputes, Allergan's proposal provides general guidelines on confidentiality designation and specifies that, among other things, Allergan's NDA, Taro's ANDA, and associated Drug Master Files—documents that go to the heart of nearly all patent disputes arising under the Hatch-Waxman Act—may only be designated Confidential, not Highly Confidential. *Id.*

Taro seeks to omit these provisions, which would allow it to designate as Highly Confidential any technical or regulatory documents that it might produce, and has made clear that it intends to designate its entire ANDA as Highly Confidential, inviting Allergan to negotiate access to portions of the ANDA, a document with thousands of pages and numerous sections, on a piecemeal basis. Ex. C, Oct. 24, 2017 E-mail from K. Beis.

A. Taro's bar against in-house counsel access to the ANDA is improper.

Taro cannot meet its burden of justifying the Highly Confidential designation for its ANDA.³ In-house counsel access to information is integrally linked to a party's ability to make informed decisions, and the usual practice is to allow in-house counsel access to all information.⁴ Taro's ANDA is the type of information to which Allergan needs access in order to make informed litigation decisions. Although this consideration would be present in any ANDA case in which infringement is at issue, Taro contends in this case that "Allergan has no basis to maintain its lawsuit" on grounds that its ANDA product does not infringe. D.I. 22 at 1. But the ANDA itself is the single most important document relating to infringement, and Taro has attempted to deny Allergan's in-house counsel the right to review it.

Moreover, Taro has not raised any objection to the two specific in-house counsel designated by Allergan. Taro's unwillingness to permit in-house counsel access is categorical, and based solely on an individual's status as in-house counsel—an approach contrary to well-established precedent of this and other courts.⁵ As the Federal Circuit has explained in *U.S. Steel*,

³ See Fed. R. Civ. P. 26(c); *In re Deutsche Bank Trust Co.*, 605 F.3d 1373, 1378 (Fed. Cir. 2010) ("A party seeking a protective order carries the burden of showing good cause."); *United States v. Wecht*, 484 F.3d 194, 211 (3d Cir. 2007) ("[T]he burden of justifying the confidentiality of each and every document sought to be covered by a protective order remains on the party seeking the protective order.") (citation omitted).

⁴ See also *Apeldyn Corp. v. AU Optronics Corp.*, No. 08-568-SLR, 2012 WL 2366537, at *1 n.1 (D. Del. June 20, 2012); *Eurand, Inc. v. Mylan Pharm., Inc.*, No. 08-889-SLR, ECF No. 71, at 2 (D. Del. June 23, 2009); *ArthroCare Corp. v. Gyrus Med., Inc.*, No. 07-729-SLR (D. Del. Jan. 28, 2009), Tr. at 32:11–14, Ex. D; *AutoZone Inc. v. Tri-State Auto Outlet, Inc.*, No. 04-103-SLR (D. Del. Aug. 3, 2004), Tr. at 11:13–23, Ex. E; *Avery Dennison Corp. v. Minn. Mining & Mfg. Co.*, No. 01-125-JJF, 2001 WL 1339402, at *2 (D. Del. Oct. 26, 2001) ("[A]llow[ing] the parties to craft a protective order that places adequate safeguards on the use and mode of reviewing *all* sensitive information, but that does not deny designated in-house counsel access to that information" (emphasis added)).

⁵ *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1469 (Fed. Cir. 1984); *Matsushita Elec. Indus. Co. v. United States*, 929 F.2d 1577, 1579 (Fed. Cir. 1991); *R.R. Donnelley & Sons Co. v. Quark, Inc.*, No. 06-032-JJF, 2007 WL 61885, at *1 (D. Del. Jan. 4, 2007); *Boehringer Ingelheim Pharm., Inc. v. Hercon Labs. Corp.*, No. 89-484-CMW, 1990 WL 160666, at *1 (D.

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“status as in-house counsel cannot alone create that probability of serious risk to confidentiality and cannot therefore serve as the sole basis for denial of access.”⁶

Taro’s approach is not only generally disfavored, but also is specifically unjustified in this case. To date, the only reason Taro has offered in support of its position is that Allergan is prosecuting pending patent applications relating to dapstone topical products and that confidential information could be improperly used for that purpose.⁷ But any such risk of improper use is already addressed by multiple safeguards in the protective order. *E.g.*, Ex. A ¶¶ 13, 14(b), 42, 51. First, the order limits access to in-house counsel who are *not* competitive decision-makers. Ex. A ¶ 14(b). As the Federal Circuit has explained, an individual’s participation in competitive decision-making is the key inquiry in determining whether to grant the individual access to confidential information.⁸ Moreover, the parties have agreed to subject anyone with access to confidential information, including designated in-house counsel, to a stringent patent prosecution bar. Ex. A ¶ 14(b). Allergan even accepted Taro’s edits to the prosecution bar to tailor it to Taro’s satisfaction. *Compare* Ex. A ¶ 14(b), *with* Ex. B ¶ 14(b) (Taro’s edits to Allergan’s initial proposal). Under those provisions, designated in-house counsel may not contribute, directly or indirectly, to patent prosecution relating to dapstone gel products. Notably, despite its putative concern here, Taro has consented to in-house counsel access to its ANDA, even when the plaintiff had pending applications related to the asserted patent, in at least one other case.⁹

Absent a showing of good cause, Taro should not be permitted to designate its ANDA Highly Confidential and preclude Allergan in-house counsel access. Alternatively, should the Court be unwilling to prohibit Taro from designating its ANDA as Highly Confidential, Allergan would agree to entry of a Protective Order with a single confidentiality tier, to which its two in-house counsel would have access.

B. Taro’s proposal to allow piecemeal access to the ANDA should be rejected.

Taro’s counsel has suggested that the dispute may be avoided by having Allergan petition Taro to designate portions of its ANDA as Confidential, rather than Highly Confidential. Ex. C, Oct. 24 E-mail from K. Beis. Taro’s proposal improperly shifts the burden of making confidentiality designations to the requesting party.¹⁰ Moreover, Taro’s proposal is untenable: it would force Allergan to negotiate with Taro piecemeal on a document-by-document, or even line-by-line, basis—revealing in the process what Allergan’s outside counsel intend to discuss with its in-house counsel. And because Taro apparently regards its entire ANDA as Highly

Del. Oct. 12, 1990) (“The status of in-house counsel is not viewed by this Court as warranting automatic exclusion from confidential information produced under a protective order.”).

⁶ *U.S. Steel*, 730 F.2d at 1469.

⁷ Ex. F, Rule 16 Conference Tr. at 29:17–30:8.

⁸ *Deutsche Bank*, 605 F.3d at 1378; *U.S. Steel*, 730 F.2d at 1468 & n.3; *see also id.* at 1469.

⁹ Ex. G, *Merz Pharm. LLC v. Taro Pharm. U.S.A., Inc.*, No.15-3720-WHP-SN, ECF No. 32, at 6 (S.D.N.Y. Nov. 12, 2015) (protective order); Ex. H, PTO continuity data of asserted U.S. Patent 8,778,365 (showing pending applications as of the date the protective order was entered); Ex. I (complaint showing U.S. Patent 8,778,365 as the patent-in-suit).

¹⁰ *See Wecht*, 484 F.3d at 211.

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Confidential (with the possible exception of a single-page list of ingredients), there is little chance it will retreat from its current position and allow Allergan's in-house counsel access to it, and every reason to believe Allergan will be required to repeatedly resort to the Protective Order's time-consuming and difficult dispute resolution process. *See* Ex. A ¶ 22.

II. The Court should not permit Taro's request for access for non-attorney employees.

Taro's request to allow its non-attorney IP personnel to access Allergan's confidential information should be denied. *See* Ex. A ¶ 14(b). Taro has already designated a qualified U.S. in-house attorney, Mr. Craig Kuchii, to receive Allergan's confidential information. *Id.*¹¹

Taro's designation of one additional yet-to-be named non-attorney presents a significant risk to Allergan's confidential information. The court has recognized that limiting access to in-house counsel minimizes disclosure risk because, "[l]ike outside counsel, in-house counsel is bound by professional and ethical responsibilities and their conduct is subject to sanctions."¹² Under Taro's proposal, Allergan would be sharing confidential information with an employee of a direct competitor who is not bound by the same professional obligations as an in-house attorney.¹³ Worse, that employee will likely be located in a foreign country—Taro has told Allergan during a meet-and-confer that the employee will likely be in India—and outside the Court's jurisdiction. The potential of misuse or improper disclosure of confidential information thus counsels against allowing Taro's request,¹⁴ which should be denied.

* * * * *

For all these reasons, Allergan respectfully requests that the Court enter Allergan's proposed protective order.

¹¹ *Cosmo Technologies Ltd. v. Lupin Ltd.*, No. 15-669-LPS, D.I. 56 (D. Del. Jul. 28, 2016) ("Given that [defendant] has already designated one in-house attorney working as litigation counsel to receive Plaintiffs' confidential information and to advise [defendant] in this litigation, the Court is not persuaded that [defendant] will be unfairly disadvantaged if non-attorney staff, who lack the same professional obligations and are more likely involved in competitive decision making, are prohibited from accessing such information.").

¹² *Avery Dennison*, 2001 WL 1339402, at *2 (citing *Boehringer*, 1990 WL 160666, at *2).

¹³ *See, e.g., U.S. Steel*, 730 F.2d at 1468 ("[I]n-house counsel are officers of the court, are bound by the same Code of Professional Responsibility, and are subject to the same sanctions.").

¹⁴ *Phillips Petroleum Co. v. Rexene Prods. Co.*, 158 F.R.D. 43, 46 (D. Del. 1994) (barring non-attorney designee due to, among other things, the potential of improper use); *Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20, 22 (D. Del. 1988) (barring plaintiff's non-attorney president in favor of in-house counsel due to the potential for competitive harm).

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Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

JBB/dlw

Enclosures

cc: Clerk of Court (Via Hand Delivery; w/ encl.)
All Counsel of Record (Via Electronic Mail; w/ encl.)